IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steven Z. Wu *et al.*		Examiner: Humera N. Sheikh	
Serial No.	10/663,568	Art Unit:	1615
Filed:	September 15, 2003	Confirmation No.: 2840	
Title:	Microparticle Coated Medical Device		

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Commissioner for Patents
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SECOND APPEAL BRIEF

Sir or Madam:

On October 25, 2010, Applicants reinstated an appeal to the Board of Patent Appeals and Interferences from the rejection of claims 25, 28-32, and 34-37. A previous Appeal Brief had been filed February 17, 2010. The fees for that appeal should be applied to this appeal. The following is Applicants' (Second) Appeal Brief submitted pursuant to 37 C.F.R. § 41.37. It is respectfully requested that this submission be considered a petition for extension of time sufficient to make this a timely filing with respect to the Notice of Appeal filed October 25, 2010.

I. REAL PARTY IN INTEREST

The real party in interest is Advanced Cardiovascular Systems Inc., a California corporation, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The assignment was recorded in the United States Patent and Trademark Office for the parent application, 09/851877, now US Patent No. 6,656,506, on May 9, 2001, in Reel 011800, Frame 0894. Effective February 13, 2007, Advanced Cardiovascular Systems Inc. changed its name to Abbott Cardiovascular Systems Inc.

II. RELATED APPEALS AND INTERFERENCES

Applicants, applicants' assignee, and their counsel are not aware of any related appeals or interferences which would affect, be affected by, or have a bearing on the instant appeal.

III. STATUS OF CLAIMS

Claims 25, 28-32, and 34-37 have been rejected by the Examiner; the rejections thereof are being appealed herewith. Claims 1-24, 26, 27, and 33 have been previously canceled.

IV. STATUS OF AMENDMENTS

All amendments of record have been entered by the Examiner. There have been no responses or amendments submitted after the most recent Office Action of May 24, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 25[1] is directed to a drug loaded stent comprising: a) a radially expandable stent body; b) a coating layer disposed on the stent body; and c) polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made, wherein the coating layer is free from any therapeutic substances (*see, for example,* specification page 3, lines 25-33; page 6, lines 31-34 and Figure 2; page 12, line 29 to page 13, line 24; page 14, line 28 to page 15, line 2; "Method 1" of page 16; and "Method 3" of page 16).

Claim 32[2] is directed to a medical device comprising an implantable substrate and a coating layer, wherein the coating layer is free from any therapeutic substances but includes particles of a polymeric material having a therapeutic substance added thereto, wherein the therapeutic substance is completely encased within the polymer particles (*Id*).

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[1] 25. A drug loaded stent, comprising:

a radially expandable stent body,

a coating layer disposed on the stent body, and

polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made, wherein the coating layer is free from any therapeutic substances.

[2] 32. A medical device, comprising an implantable substrate and a coating layer, wherein the coating layer is free from any therapeutic substances but includes particles of a polymeric material having a therapeutic substance added thereto, wherein the therapeutic substance is completely encased within the polymer particles.

Claim 36[3] is directed to an implantable medical device made by the method that includes adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material. The coating material includes a polymeric material dissolved in a solvent. The polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent. The method also includes applying the fluid form of the coating material comprising the polymeric particles added thereto to an implantable medical device. The method further includes solidifying the coating material to a film layer by allowing the solvent to evaporate, wherein the film layer includes the polymeric particles containing the therapeutic substance. (*Id*).

Claims 25, 32, and 36 have been duplicated in the footnotes as they form a primary basis for this appeal.

Applicants have identified several advantages of the invention and these advantages can serve as evidence of non-obviousness of the claims of the present application. Having a coating layer that is free from any therapeutic substances is important because it allows for greater control of the release of the loaded microparticles containing the therapeutic substance. The use of microparticles allows for higher drug-loading at a particular target site. In addition, in the past, "drug release rates may also be inadequate since the rate at which the drug is released or delivered to the target site is a

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[3] 36. An implantable medical device made by the method comprising:

adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material, wherein the coating material includes a polymeric material dissolved in a solvent, and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent;

applying the fluid form of the coating material comprising the polymeric particles added thereto to an implantable medical device; and

solidifying the coating material to a film layer by allowing the solvent to evaporate, wherein the film layer includes the polymeric particles containing the therapeutic substance.

function of the chemical and/or biological properties of the polymer in which the drug is embedded." (specification, page 2, lines 25-28).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are the specific grounds of rejection exactly as set forth in the Office Action of May 24, 2010, at pages 2-11. In summary, those rejections are (A) the rejection of claims 25 and 32 under 35 U.S.C. 112, first paragraph, as allegedly non-enabled; (B) the rejection of claims 25 and 32 under 35 U.S.C. 112, second paragraph, as alleged indefinite; (C) the rejection of claims 32, 34, 36, and 37 as being anticipated under 35 U.S.C. 102(e) by U.S. Patent No. 6,099,562 of Ding *et al.* ("Ding"); and (D) the rejection of claims 25, 28-31, and 35 as being obvious under 35 U.S.C. 103(a) over Ding in view of U.S. Patent Application Publication No. 2002/0133183 of Lentz *et al.* ("Lentz") and further in view of U.S. Patent No. 5,886,026 of Hunter *et al.* ("Hunter").

VII. ARGUMENTS

Applicants respectfully submit that, as will be explained below, each of the rejections of each of the claims is improper, and is not supported by sufficient evidence of record. Accordingly, Applicants respectfully request reversal of the rejections.

A. Claims 25 and 32 are enabled and consequently comply with 35 U.S.C. 112, first paragraph.

The Examiner's position is that claims 25 and 32 are not enabled. The Examiner contents, "Applicant has not shown how to make and obtain a drug-free coating, particularly in view of the fact that the coating layer comprise polymeric particles containing a therapeutic substance." (Office Action, dated May 24, 2010, page 3 -- herein after "Office Action")

As is axiomatic in patent law, an analysis of whether a claim fulfills 112, first paragraph is whether that disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim as to enable one skilled in the art to make and use the claimed invention. As was defined in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916), the issue is whether experimentation needed to practice the invention undue or unreasonable. (*see also*, *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) "The test of enablement is whether one reasonable skill in the art could make or use the invention from the disclosures in the patent coupled with information know in the art without undue experimentation.")

Based on this foundation, Applicants respectfully submit that the Examiner is in clear error and that the specification unequivocally describes how to make and use the invention without undue experimentation, so as to satisfy 35 U.S.C. 112, first paragraph.

Figure 2 illustrates a stent or medical substrate, labeled as "12". Figure 2 further shows coating layer 18. Coating layer 18 is described in the specification as to be free from any drugs. Polymeric particles 20 contain or are completely encasing the therapeutic substance. The coating layer 18 holds the polymer particles 20 on the stent or

medical device while the device is inserted at a target location for treatment or diagnostic purposes.

With Figure 2 in view, the Honorable Board's attention is next drawn to page 6, last paragraph which notes that "the entire surface of stent 10 can be coated with a polymer solution 18, which includes a suspension of drug-loaded microparticles 20, such as microspheres and/or nanospheres." (emphasis added). Examples 1-8 of pages 8 to 12 teach methods of making the particles which include a drug. This is followed by the description of page 12, line 29 to page 14, line 31. Most significantly, "Method 1" (and Method 2" to "Method 6") on page 16 teaches how to produce the coating of Figure 2 with, for example, the microparticles described in Examples 1-8.

In sum, Applicants have provided ample description to allow one skilled in the art to make and use the inventive claims without undue experimentation. It should be exceedingly clear from the above that "free from any therapeutic substances" refers to the coating (18) itself, which is formed from a solution without any dissolved therapeutic substances. The microparticles (20) are suspended in this solution, but do not dissolve in the solution. Thus, therapeutic substances are held on the stent (12) by the layer 18, but are not part of the layer 18 from the standpoint of the claim. The cited portions of the specification fully enable the practice of this invention.

B. Claims 25 and 32 are definite and consequently with 35 U.S.C. 112, second paragraph.

The Examiner is now contending that claims 25 and 32 are indefinite because "it is confusing and unclear as to how the coating layer can 'be free from any therapeutic substances' when the claim explicitly recites 'polymeric particles containing a therapeutic substance.'" (emphasis added)

Applicants respectfully respond in two parts:

First, the above-noted limitation, which has been deemed "confusing and unclear" has been in the claims since the filing date of the application (original dependent claims 27 and 33, then moved to their respective independent claims 25 and 32). When the Examiner issued an office action on 9/22/2006, the Examiner certainly did not find this limitation "confusing and unclear." When the Examiner issued the second office action

on 4/4/2007, yet again, the Examiner had no objection to this limitation. Next, when a pre-appeal brief was filed on 5/29/2007 and prosecution re-opened resulting in yet a new office action dated 12/19/2007, this limitation appeared to be rather clear to the Examiner. The same holds true for the office actions issued on 5/23/2008, 11/10/2008, and 5/22/2009 as well as the advisory action of 8/6/2009, in which no objection was raised. The claims have suffered through 7 office actions, 1 pre-appeal brief and one formal appeal (this current appeal being the second appeal), during which time, the Examiner has been purportedly, and by all accounts, not "confused and unclear" on the subject matter that was being examined. Applicants respectfully submit that is grossly unfair and unreasonable to the Applicants, both in lost time and expenses, to have to endure 7 office action without any hint that the subject matter of the claims have for all this time been "confusing and unclear" to the Examiner.

Second, as indicated in the preceding section with respect to lack of enablement, one need not look beyond Figure 2 to understand the scope of the claims. Figure 2 illustrates a stent or medical substrate, labeled as "12". Figure 2 further shows coating layer 18. Coating layer 18 is described in the specification as to be free from any drugs. Polymeric particles 20 contain or are completely encasing the therapeutic substance. The coating layer 18 holds the polymer particles 20 on the stent or medical device 12 while the device is inserted at a target location for treatment or diagnostic purposes.

With Figure 2 in view, the Honorable Board's attention is next drawn to page 6, last paragraph which notes that "the entire surface of stent 10 can be coated with polymer solution 18, which includes a suspension of drug-loaded microparticles 20, such as microspheres and/or nanospheres." (emphasis added). Examples 1-8 of pages 8 to 12 teach methods of making the particles which include a drug. This is followed by the description of page 12, line 29 to page 14, line 31. Most significantly, "Method 1" (and Method 2" to "Method 6") on page 16 teaches how to produce the coating of Figure 2 with, for example, the microparticles described in Examples 1-8.

In summary, in light of the specification, it is abundantly clear that "free from any therapeutic substances" refers to the coating itself (reference number 18 of Figure 2), which is formed from a solution without any dissolved therapeutic substances. In contrast, the microparticles -- containing or encasing the therapeutic substances -- are

suspended in this solution, but do not dissolve in the solution. Thus, therapeutic substances are held on the stent by the layer 18, but are not part of the layer 18 from the standpoint of the claim. The cited portions of the specification provide the light necessary so that the metes and bounds of the invention can be clearly understood without self-contradiction.

C. Claims 32, 34, 36, and 37 are novel with respect to U.S. Patent No. 6,099,562 of Ding *et al.* ("Ding")

As outlined in MPEP 2131, in order for a reference to anticipate a claim, the reference must teach every element of the claim. A claim is only anticipated if each and every element of the claim is described, either inherently or expressly, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987).

It is a requirement for a proper anticipation rejection under 35 U.S.C. § 102 that "'[t]he identical invention must be shown in **as complete detail** as is contained in the ... claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)" (emphasis added). Moreover, "[e]very element of the claimed invention must be literally present, **arranged as in the claim**." *Id.* (emphasis added).

It is respectfully submitted that the present rejection does not meet the above standard with respect to the rejection of each of the rejected claims. Accordingly, it is respectfully submitted that the rejections must be reversed for the reasons set forth below.

1. Claim 32 is novel over Ding

The Office Action, on page 4, notes that Ding teaches that "[t]he coating is preferably applied as a mixture, solution, or suspension of polymeric materials and finely divided biologically active species dispersed in an organic vehicle or a solution or partial solution of such species in a solvent or vehicle for the polymer and/or biologically active species (col. 4, lines 8-13)." The Examiner, then contends that "[t]his reads on Applicant's medical device having a 'coating layer wherein the therapeutic substance completely [sic] encased within the polymer particles' and a 'film layer including polymeric material encasing the polymeric particles'."

The Examiner interpretation of Ding as well as the claims is grossly misdirected.

Ding, without any uncertainty, teaches a coating layer 103 having particles of a drug 105 -- as clearly depicted by Figure 9, which also appears on the cover of the patent. A top-coat layer 104 covers the polymer + drug layer 103. Col. 4, lines 8 to 21, as relied upon by the Examiner states:

> In the process, the initial coating is preferably applied as a mixture, solution or suspension of polymeric material and finely divided biologically active species dispersed in an organic vehicle or a solution or partial solution of such species in a solvent or vehicle for the polymer and/or biologically active species. For the purpose of this application, the term "finely divided" means any type or size of included material from dissolved molecules through suspensions colloids and particulate mixture. The biologically active material is dispersed in a carrier material which may be the polymer, a solvent or both. The coating is preferably applied as a plurality of relatively thin layers sequentially applied in relative rapid sequence and is preferably applied with the stent in a radially expanded state.

What this paragraph simply teaches is that a solution or partial solution of a polymer + solvent + drug is applied to a stent. The polymer can be mixed, in solution or suspended, with the solvent. The drug (biological active species), and not the polymer, can be finely divided in colloids or particles.

Once the organic vehicle (i.e., solvent) is removed, the polymer coalesces into a homogeneous layer. This homogeneous layer carries the drug particles. The polymer is not in particle form encasing the active species or the drug. This submission has unequivocal and indisputable support in Ding.

First, the polymer, once deposited and the solvent is removed, is referred to as a "layer" throughout the specification and not particles (which encase the active species). Not once is the term "particle" used in reference to the deposited polymer. Second, a homogenous layer and not particles is clearly depicted by Figure 9 - reference number 103. Third, the specification, which should be considered in context and in whole, refers to the mixture as "a homogenous composition" (see, for example, col. 9, line 5, col. 9, lines 27-31, describing the solution as "homogenous" or "milk-like.") Figure 1 (which is a flow diagram of the Ding invention), block 14, further supports the proposition that the polymer composition is homogenized.

In sum, nowhere in Ding is there any mention of "polymeric particles" and further

"the therapeutic substance [being] completely encased within the polymeric particles" as recited by claim 34. The only mention of "particles" is for the drug in and of itself (see, for example col. 4, line 54 and col. 13, line 35). Thus, for at least this reason, the rejection is improper.

Moreover, the Office Action cited a different layer of Ding as corresponding to the claimed element of "the coating layer [being] free from any therapeutic substances." In other words, the Examiner is contending that that topcoat 104 of Figure 9 is free from any drugs and it covers particles of an undercoat polymer encasing a drug. Such a mapping between the claims and the prior art is plainly improper. The claim requires that the layer that is itself "free from any therapeutic substances" is the same layer that includes, embedded therein, the polymer particles that completely encase the therapeutic substance. Accordingly, for this additional reason, the rejection is improper. Thus, reversal of the rejection is respectfully requested.

2. Claim 34 is novel over Ding

Claim 34 has been rejected as being anticipated by Ding. Claim 34 depends from independent claim 25. Claim 25 has not been rejected as being anticipated by Ding. This rejection is improper.

3. Claim 36 is novel over Ding

Claim 36 recites, "adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material." There is no disclosure of these features in Ding. It is unclear what the Office Action believed was the disclosure in Ding corresponding to "adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material." However, upon careful review of Ding, no corresponding disclosure could be located.

There is discussion in Ding, at column 4, lines 8-21, of the initial coating that is applied:

> In the process, the initial coating is preferably applied as a mixture, solution or suspension of polymeric material and finely divided biologically active species dispersed in an organic vehicle or a solution or partial solution of such

> species in a solvent or vehicle for the polymer and/or biologically active species. For the purpose of this application, the term "finely divided" means any type or size of included material from dissolved molecules through suspensions colloids and particulate mixtures. The biologically active material is dispersed in a carrier material which may be the polymer, a solvent, or both. The coating is preferably applied as a plurality of relatively thin layers sequentially applied in relatively rapid sequence and is preferably applied with the stent in a radially expanded state.

There is not, however, any discussion in that paragraph of "adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material," as recited in claim 36. Thus, Ding does not anticipate claim 36.

Moreover, claim 36 recites: "wherein the coating material includes a polymeric material dissolved in a solvent, and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent." Ding also does not disclose such features. While Ding makes reference generally to a "suspension" in the paragraph quoted above, Ding does not disclose or suggest the features, "wherein the coating material includes a polymeric material dissolved in a solvent, and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent." Thus, for this additional and alternative reason, Ding does not anticipate claim 36. Reversal of the rejection of claim 36 is respectfully requested.

4. Claim 37 is novel over Ding

Claim 37 depends from claim 36. Thus, the rejection of claim 37 should be reversed for at least the same reasons that the rejection of claim 36 should be reversed. Claim 37 further recites: "wherein the film layer includes the polymeric material encasing the polymeric particles." There is no discussion in Ding of any polymeric material encasing polymeric particles. Accordingly, Ding does not disclose or suggest at least these further features of claim 37. Thus, for this additional and alternative reason, it is respectfully requested that the rejection of claim 37 be reversed.

D. Claims 25, 28-31, and 35 are non-obvious with respect to Patent No. 6,099,562 of Ding *et al.* ("Ding") in view of U.S. Patent Application Publication No. 2002/0133183 of Lentz *et al.* ("Lentz") and further in view of U.S. Patent No. 5,886,026 of Hunter *et al.* ("Hunter").

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, (2007)

Indeed, in rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A *prima facie* case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed combination or other modification. *See In re Lintner*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972); *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442-43 (Fed. Cir. 1991) (explaining the three elements of a *prima facie* case of obviousness include: (1) motivation for the combination, (2) a reasonable expectation of success, and (3) a disclosure of all the claim elements by the prior art). *See also In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974).

Furthermore, the conclusion that the claimed subject matter is *prima facie* obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Rejections based on § 103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. The Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption, or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. *See In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). The Federal Circuit has repeatedly cautioned against employing hindsight by using Appellants' disclosure as a blueprint to reconstruct the claimed invention from the

isolated teachings of the prior art. *See, e.g., Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

When determining obviousness, "the [E]xaminer can satisfy the burden of showing obviousness of the combination 'only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002), citing *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). "Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact." *Dembiczak*, 175 F.3d at 999-1000, 50 USPQ2d at 1617, *citing McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993). Further, as pointed out by the Federal Circuit, the scope of the claim must be the first determination. "[T]he name of the game is the claim." *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998).

It is respectfully submitted that, for the reasons set forth below, the rejections of the claims do not meet the standard required for a *prima facie* rejection for non-obviousness. Additionally, it is respectfully submitted that the above-identified advantages of certain embodiments of the present invention are counter-evidence that demonstrates the non-obviousness of the present invention. Consequently, even if a *prima facie* obviousness rejection could be created, it should not be maintained, since the evidence of non-obviousness outweighs any evidence of obviousness.

1. Claim 25 is Non-Obvious With Respect to the Combination of Ding, Lentz, and Hunter

Claim 25 recites, "polymeric particles containing a therapeutic substance embedded within the coating layer" and "wherein the coating layer is free from any therapeutic substances." As discussed above, with respect to claim 32, Ding does not disclose these features. Lentz and Hunter cannot remedy these deficiencies of Ding, which is not surprising, because they were not cited with respect to such features. Thus,

for at least these independent and alternative reasons, the rejection of claim 25 should be reversed.

Claim 25 also recites, "wherein the coating layer comprises a polymer different than the polymer from which the particles are made." The Office Action admitted that Ding fails to disclose "wherein the coating layer comprises a polymer different than the polymer from which the particles are made." The Office Action cited Lentz with respect to this feature. However, according to the Office Action's characterization (page 8 of the Office Action), Lentz discloses "different polyfluoro copolymers may be used for different layers in the stent coating." However, such a disclosure is not equivalent to "wherein the coating layer comprises a polymer different than the polymer from which the particles are made." After all, the alleged disclosure of Lentz relates to *different layers* not to particles embedded within a layer.

Indeed, the Office Action's rationale for the alleged motivation to combine Ding and Lentz is directed to use multiple polymeric coatings. Such features would not lead to the features recited in claim 25. Thus, Lentz would not lead one of ordinary skill in the art to modify Ding to arrive at the invention recited in claim 25, because it could not cure even the Office-Action-acknowledged deficiencies of Ding with respect to claim 25.

The teachings of Hunter were not applied to claim 25, and it is respectfully submitted that no teachings of Hunter would lead one of ordinary skill in the art to modify Ding so as to arrive at the invention recited in claim 25. Thus, for all or any of these reasons, it is respectfully requested that the rejection of claim 25 be reversed.

2. Claim 28 is Non-Obvious With Respect to the Combination of Ding, Lentz, and Hunter

Claim 28 depends from, and further limits, claim 25. Thus, for at least any or all of the reasons that the rejection of claim 25 should be reversed, the rejection of claim 28 should also be reversed.

Claim 28 further recites, "wherein the polymeric particles are made from a hydrogel material." The only mention in Ding of "hydrogel" in the "related art" section. That section refers to using "a coating applied to a stent consisting of a hydrogel polymer and a preselected drug such as cell growth inhibitors or heparin." However, there is no

disclosure that such a hydrogel polymer could or should be made into polymeric particles.

Likewise, there is no mention of "hydrogel" in Lentz, whereas in Hunter, hydrogel compositions are discussed as follows: "Stents may be coated with anti-angiogenic compositions or anti-angiogenic factors of the present invention in a variety of manners, including for example: … by coating the stent with a substance such as a hydrogel which will in turn absorb the anti-angiogenic composition (or anti-angiogenic factor above) … ."

The Office Action does not make clear what part of the prior art is relied upon as allegedly teaching "wherein the polymeric particles are made from a hydrogel material." Thus, no *prima facie* rejection of claim 28 has been made. Nevertheless, based on a review of all the prior art of record, it is respectfully submitted that the prior art of record does not disclose or suggest "wherein the polymeric particles are made from a hydrogel material," as recited in claim 28. Thus, for this additional and alternative reason, it is respectfully requested that the rejection of claim 28 be reversed.

3. Claim 29 is Non-Obvious With Respect to the Combination of Ding, Lentz, and Hunter

Claim 29 depends from, and further limits, claim 25. Thus, for at least any or all of the reasons that the rejection of claim 25 should be reversed, the rejection of claim 29 should also be reversed.

4. Claim 30 is Non-Obvious With Respect to the Combination of Ding, Lentz, and Hunter

Claim 30 depends from claim 25. Thus, for at least any or all of the reasons that the rejection of claim 25 should be reversed, the rejection of claim 30 should also be reversed.

5. Claim 31 is Non-Obvious With Respect to the Combination of Ding, Lentz, and Hunter

Claim 31 depends from claim 25. Thus, for at least any or all of the reasons that the rejection of claim 25 should be reversed, the rejection of claim 31 should also be

reversed.

6. Claim 35 has Received an Improper Rejection

Claim 35 depends from, and further limits, claim 32. Claim 32 has not been rejected under Ding, Lentz and Hunter combination. Applicants respectfully submit that this rejection is improper.

Even if it was somehow proper, claim 35 recites, "wherein the coating layer comprises a polymer different than the polymer from which the particles are made." As explained above with respect to claim 25, the combination of Ding, Lentz, and Hunter fails to disclose or suggest this feature. Thus, the rejection of claim 35 should be reversed.

VIII. CONCLUSION

For all of the foregoing reasons it is submitted that all of the Examiner's rejections of claims 25, 28-32, and 34-37 were in error, and reversal of the Examiner's rejections and allowance of the application are respectfully requested.

The Commissioner is hereby authorized to charge Deposit Account No. 07-1850 for any fees due.

Date: 3/25/11

Respectfully submitted,

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Claims Appendix

25. A drug loaded stent, comprising:

a radially expandable stent body,

a coating layer disposed on the stent body, and

polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made, wherein the coating layer is free from any therapeutic substances.

28. The stent of Claim 25, wherein the polymeric particles are made from a hydrogel material.

29. The stent of Claim 25, wherein the particles are 0.5 to 2 microns in size.

30. The stent of Claim 25, wherein the therapeutic substance is for the treatment of restenosis.

31. The stent of Claim 25, wherein the therapeutic substance is a radioactive isotope.

32. A medical device, comprising an implantable substrate and a coating layer, wherein the coating layer is free from any therapeutic substances but includes particles of a polymeric material having a therapeutic substance added thereto, wherein the therapeutic substance is completely encased within the polymer particles.

34. The stent of claim 25, wherein the therapeutic substance is completely encased within the polymeric particles.

35. The medical device of claim 32, wherein the coating layer comprises a polymer different than the polymer from which the particles are made.

36. An implantable medical device made by the method comprising:

adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material, wherein the coating material includes a polymeric material dissolved in a solvent, and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent;

applying the fluid form of the coating material comprising the polymeric particles added thereto to an implantable medical device; and

solidifying the coating material to a film layer by allowing the solvent to evaporate, wherein the film layer includes the polymeric particles containing the therapeutic substance.

37. The implantable medical device of claim 36, wherein the film layer includes the polymeric material encasing the polymeric particles.

Evidence Appendix

None.

Related Proceedings Appendix

None.